A Smoking Cessation Intervention for Thoracic Surgery and Oncology Clinics

A Pilot Trial

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Introduction: Although most smokers diagnosed with lung cancer report that they want to quit smoking, many do not succeed. Smokers who quit when lung cancer is diagnosed have improved treatment efficacy, quality of life, and survival. Effective smoking cessation interventions targeted to thoracic oncology patients are needed.

Methods: This pilot study examined the feasibility and potential efficacy of a 12-week program that combined smoking cessation counseling with varenicline. Seven-day point prevalence tobacco abstinence rates at the end of treatment were compared with a usual care control group. From January 2008 to August 2009, patients with a diagnosed or suspected thoracic malignancy were recruited at their initial visit to a thoracic surgeon or thoracic oncologist at Massachusetts General Hospital.

Results: Of 1130 patients screened, 187 (17%) were current smokers, and an additional 66 (6%) reported quitting within the past 6 months. One hundred sixteen (67%) of smokers were eligible, and 49 (42%) of eligible smokers enrolled (control group $n = 17$, intervention group $n = 32$). Intervention participants completed a median of nine counseling sessions; 50% of intervention participants completed the full varenicline course. At 12-week follow-up, biochemically validated 7-day point prevalence tobacco abstinence rates were 34.4% in the intervention group versus 14.3% in the control group (odds ratio = 3.14, 95% confidence interval = 0.59–16.62, $p = 0.18$).

Conclusion: Our findings support the feasibility and acceptability of this program. At the end of treatment, quit rates were higher in the control group. Further testing is indicated to establish the efficacy of this treatment package in a randomized clinical trial.

Key Words: Lung cancer, Smoking, Cessation, Pharmacotherapy, Counseling.

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Cigarette smoking is the major cause of lung cancer, and more than 219,000 new cases of lung cancer are diagnosed each year in the United States.[1] Approximately 20 to 30% of lung cancer patients are smokers at diagnosis.[2,3] The majority of patients who receive a lung cancer diagnosis report that they want to quit smoking, but many are unable to do so.[4–6] This is unfortunate as quitting at the time of diagnosis can improve quality of life, improve chances for treatment efficacy, reduce treatment complications, reduce risk of recurrence and secondary tumors, and increase chances of long-term survival.[2,7–13]

There has never been an randomized clinical trial (RCT) for smoking cessation targeted to lung cancer patients; there have been few randomized controlled smoking cessation trials for cancer patients in general, and these trials have not demonstrated a significant intervention effect.[14] This lack of demonstrated effectiveness in tobacco treatment trials for cancer patients could be due to several factors, including low power to detect differences due to small sample sizes, lack of integration into the cancer treatment setting, and delayed smoking cessation treatment initiation.[15–19] Another potential explanation for the lack of success of smoking cessation programs for cancer patients is that most programs tested did not combine behavioral and pharmacologic treatment strategies, as the United States Public Health Service (USPHS) Treating Tobacco Use and Dependence Clinical Practice Guideline recommends.[20,21]

Varenicline, a partial agonist of the alpha-4 beta-2 nicotinic acetylcholine receptor, received Food and Drug Administration approval in 2006 as a smoking cessation aid and was recommended in the 2008 USPHS guideline as a first-line pharmacologic treatment option.[22] The efficacy of varenicline for smoking cessation in cancer patients has not been reported.

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The objective of our study was to assess the feasibility and potential efficacy of a smoking cessation treatment program that combined behavioral counseling with varenicline and was targeted to patients upon their entry into thoracic clinics.

PATIENTS AND METHODS

This study was approved by the Massachusetts General Hospital Institutional Review Board.

Study Design and Patient Recruitment

This study used a nonrandomized design, which began with a usual care control group enrollment period that was followed by an intervention group enrollment period. We recruited control group participants (January 2008 to June 2008) and intervention group participants (June 2008 to August 2009) from patients referred to thoracic surgery and oncology clinics at the Massachusetts General Hospital (MGH) in Boston, MA.

Eligibility

Inclusion criteria for both groups were the following: (1) suspected diagnosis of thoracic cancer; (2) smoked a cigarette in the past 2 weeks; (3) spoke English; (4) no metastatic disease at initial presentation; and (5) considered medically eligible by their surgeon or oncologist. In addition, a patient had to be willing to take varenicline to be eligible for the intervention group; if a patient who was otherwise eligible for the intervention group was taking nicotine replacement therapy or bupropion, he/she had to be willing to switch to varenicline. Patients with severe psychiatric illness as documented in the medical record (e.g., severe major depressive disorder and active psychosis) were cleared by their psychiatrist or primary care physician before participating in the study. We excluded patients known to have metastatic thoracic cancer before enrollment; although quitting smoking can improve physical symptoms such as ease of breathing in these patients, we felt that they would require a different focus for a smoking cessation intervention.

Enrollment and Assessment Procedures

Smoking status of patients seen in participating clinics was identified by chart review and a clinic intake form. Eligible patients provided written informed consent and completed a baseline assessment. Two and 12 weeks after enrollment, participants completed a follow-up survey. Smoking status of reported nonsmokers was biochemically confirmed by obtaining a saliva sample to test for cotinine, a nicotine metabolite. Participants who were taking nicotine replacement therapy at the time of an assessment provided an expired air carbon monoxide sample. Participants were paid $20 for completing each of the assessments.

Intervention

Intervention participants were provided with a 12-week program consisting of varenicline (1 mg twice a day, with initial titration up over week 1) and smoking cessation counseling targeted to the issues of thoracic cancer patients. We had proposed to offer seven counseling sessions but were flexible in offering additional sessions when needed. The counseling was delivered by a certified Tobacco Treatment Counselor using motivational interviewing techniques.[23] Motivational interviewing is a counseling style that seeks to enhance individuals' readiness to change behavior by emphasizing a smoker's choice, personal responsibility, and self-efficacy.

The initial counseling session took place during the baseline visit or by telephone within 48 hours of study enrollment and focused on the cancer-specific benefits of quitting smoking, forming a quit smoking plan, and instructions on study medication use and adherence. Follow-up counseling sessions were conducted by telephone, or in person when possible, with standardized counseling modules. All sessions were structured according to the five As brief counseling model (Ask, Advise, Assess, Assist, Arrange follow-up) and included cancer-specific and general smoking cessation and relapse prevention topics.[22] Intervention content was selected based on the principal investigator's previous work,[24,25] published smoking cessation work with cancer patients, and lessons learned about the population during the control group observation period (e.g., high levels of environmental tobacco smoke). We targeted modifiable factors that previous research has shown associated with cancer patients' quitting and staying quit: emotional distress (lower anxiety and depression scores) and smoking and cancer beliefs (higher perceived risk of cancer recurrence, higher self-efficacy to quit, and higher quit motivation).[5,17,18,20,26–33]

Measures

Sociodemographics

At baseline, age, gender, race/ethnicity, education, marital status, and employment were assessed with a questionnaire and medical record review.

Cancer and Medical History

Previous cancer history and family history of lung disease, cancer, and heart disease were collected from the clinic screening form. Cancer status variables (diagnosis, stage, and treatment modalities) were abstracted from the medical records.

Psychosocial Factors

Emotional support was measured at baseline and follow-up using four items from the emotional/informational scale of the Medical Outcomes Study social support survey, a reliable scale ($\alpha = 0.96$) that has been widely used with cancer patients.[34–37] Smoking-specific support was measured at baseline and follow-up using a single, Likert-type, response item. Depression and anxiety symptoms were measured at baseline and follow-up via the Hospital Anxiety and Depression Scale,[38] a 14-item assessment of mood with depression and anxiety subscales that has been well tested in cancer patients.[35,38–40] Participants with scores ≥ 8 on the depression or anxiety subscales were considered to have elevated levels of depressed mood or anxiety. Participants rated current levels of pain and stress at baseline and follow-up on a 0 to 10 scale.[41]

Smoking Characteristics

Smoking history (years smoked and past cessation treatment) was assessed in the baseline questionnaire. Current nicotine dependence was measured at baseline using the two

items from the Fagerström Test for Nicotine Dependence (FTND),[42–44] which have been found to account for the bulk of the predictive validity of the FTND: number of cigarettes per day and time to first cigarette after waking. Smoking environment (live with a smoker and home policy) was assessed at baseline and follow-up. Participants were asked to rate, on a 10-point scale, their attitudes about quitting smoking (the importance of quitting smoking and confidence in ability to quit) and knowledge about the benefits of quitting smoking after a cancer diagnosis.

Feasibility

Feasibility was assessed by rates of study eligibility, recruitment, retention, and intervention adherence (counseling and medication).

Smoking Outcome

Seven-day point prevalence abstinence ("Have you smoked a cigarette, even a puff, in the past 7 days?") was assessed at 2- and 12-week follow-up points. Self-reported abstinence was confirmed only if a salivary cotinine level was less than 15 ng/ml or an expired carbon monoxide measurement was less than 10 ppm. Some participants returned saliva samples with insufficient quantity for cotinine assay. For the primary analysis, participants who did not complete the survey or return analyzable saliva samples were considered to be smokers. A secondary analysis counted self-reported nonsmokers who returned saliva samples with insufficient quantity for assay as nonsmokers.

Data Analysis

All data analyses were conducted using SPSS 18.0. Using χ^2 tests and one-way analyses of variance, we compared the sociodemographics and smoking histories of eligible participants who enrolled with those who declined to enroll to determine whether study participants were similar to the MGH thoracic patient population. A similar analysis explored the comparability of the intervention and usual care control groups. The primary outcome measure, biochemically confirmed 7-day point prevalence tobacco abstinence as defined above, was compared between groups using a univariate logistic regression. Analyses examined variables associated with 12-week smoking status with participants from both treatment groups. Logistic regressions were conducted with baseline characteristics of interest as the independent variable and then with changes in intervention targets predicting 12-week smoking status.

RESULTS

Recruitment

We screened 1130 patients in the MGH thoracic surgery and oncology clinics; 187 (17%) identified themselves as smokers, and an additional 66 (6%) reported quitting within the past 6 months (Figure 1). Of the current smokers in whom eligibility could be assessed, 116 (67%) were eligible, and 49 (42%) enrolled. The most common reason for ineligibility was having metastatic cancer. The main reason for declining participation was reluctance to take varenicline.

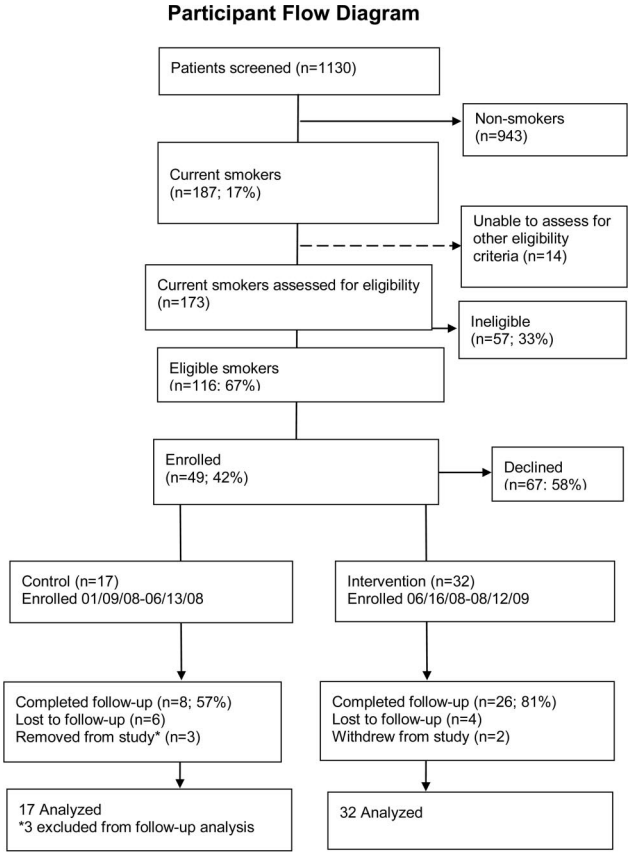

FIGURE 1. Study recruitment and retention. *Three control participants were removed due to ineligibility status that emerged after recruitment (metastatic disease, nonsurgical status); subsequently, the decision was made to retain patients, regardless of their postenrollment disease/treatment status.

Other reasons for refusal included preferring to quit on one's own, having no interest in quitting, feeling overwhelmed, or not having time to participate. Those who enrolled did not differ from those who refused in terms of sociodemographic characteristics, medical history, or past use of nicotine replacement therapy or bupropion (all $p > 0.05$). However, those who enrolled were significantly more likely to report using or having used varenicline (34.8% versus 12.8%; $p = 0.02$) and marginally more likely to have used smoking cessation counseling in the past (31.0% versus 14.8%; $p = 0.06$). Enrollees had higher rates of anxiety (55.9% versus 26.1%; $p = 0.007$).

Participants

Tables 1 and 2 display the characteristics of the 49 participants; 59.2% were female, 87.8% were white, and the mean age was 57.7 years. The intervention and control group participants did not differ significantly in sociodemographic factors, smoking history, or medical history. Most participants were long-term, highly dependent smokers with low levels of confidence in their ability to quit. Only 31.0% had ever used smoking cessation counseling, and 64.4% had ever

TABLE 1. Sociodemographic, Medical, and Psychosocial Characteristics of Participants

Variable	All (N = 49)	Control (N = 17)	Intervention (N = 32)	p
Sociodemographics				
Age, mean (SD)	57.7 (12.4)	58.0 (10.5)	57.5 (13.4)	0.90
Female (%)	59.2	52.9	62.5	0.56
White, non-Hispanic (%)	87.8	94.1	84.4	0.65
Education (%)				
<High school	12.2	5.9	15.6	0.65
High school/GED	36.7	35.3	37.5	
>High School	51.0	58.8	46.9	
Marital status (%)				
Married/living with a partner	49.0	52.9	46.9	0.69
Widowed/divorced/separated	32.7	35.3	31.3	
Never married	18.4	11.8	21.9	
Employed (%)	49.0	58.8	43.8	0.38
Medical history				
Past history of cancer (%)	18.9	23.5	15.0	0.68
Thoracic cancer diagnosis (%)	66.0	58.8	70.0	0.53
Cancer treatment (%)				
Surgery only	57.6	72.7	50.0	0.45
Chemotherapy ± radiation	30.3	18.2	36.4	
Surgery + chemotherapy/radiation	12.1	9.1	13.6	
Psychosocial factors				
Emotional support, mean (SD)[a]	3.5 (1.3)	3.8 (1.5)	3.4 (1.2)	0.26
Smoking-specific support, mean (SD)[b]	3.7 (0.67)	3.8 (0.4)	3.6 (0.8)	0.40
HADS Anxiety subscale ≥8 (%)[d]	63.3	52.9	68.8	0.34
HADS Depression subscale ≥8 (%)[d]	34.7	35.3	34.4	1.00
Stress rating, mean (SD)[c]	6.4 (3.1)	6.4 (3.2)	6.4 (3.0)	0.98
Pain rating, mean (SD)[c]	3.3 (3.3)	3.8 (3.6)	3.0 (3.1)	0.44

[a] Emotional support, 1–5 scale; 1 = none of the time, 5 = all of the time.
[b] Smoking-specific support, 1–4 scale; 1 = none, 4 = a lot.
[c] Pain and stress, 0–10 scale; 0 = no pain/stress, 10 = worst pain/stress imaginable. [d]Hospital Anxiety and Depression Scale (HADS), >8 on the depression or anxiety subscales = elevated levels of depressed mood or anxiety.
GED, General Equivalency Diploma.

used pharmacotherapy. Participants generally agreed that quitting would reduce the risk of treatment complications and the risk of future tumors.

Intervention Adherence

Participants in the intervention group completed a median of nine counseling sessions and had a median of 88 minutes of total counseling contact time. The average initial contact was approximately 20 minutes, and the follow-up sessions were approximately 10 minutes. Participants received an average of six counseling sessions before initiating cancer treatment, which started a mean of 51 (SD=45.2) days after study enrollment (Figure 2). Half of the participants who took varenicline completed the full treatment course, and 23.3% took the medication for 4 to 8 weeks. The most common side effect was nausea, reported by one-third of participants; eight (26.7%) participants discontinued the medication due to side effects (seven for abnormal dreams and/or nausea and one for feelings of agitation/aggression).

Smoking Cessation Rates

Self-reported nonsmokers complied with 97% of requests for saliva samples (Table 3). Using the conservative method of considering participants with insufficient saliva samples as smokers (Table 3, version 2), cotinine-confirmed 7-day point prevalence abstinence rates were 28.1% in the intervention group versus 14.3% in the control group (odds ratio [OR] = 2.35, 95% confidence interval [CI] = 0.44–12.64, p = 0.32) at 2-week follow-up and 34.4% in the intervention group versus 14.3% in the control group (OR = 3.14, 95% CI = 0.59–16.62, p = 0.18) at 12-week follow-up. In a secondary analysis that considered participants with insufficient cotinine samples as nonsmokers (Table 3, version 1) cotinine-confirmed 7-day point prevalence abstinence rates were 37.5% in the intervention group versus 28.6% in the control group (OR = 1.50, 95% CI = .38–5.86, p = 0.56) at 2-week follow-up and 40.6% in the intervention group versus 14.3% in the control group (OR = 4.11, 95% CI = 0.79–21.48, p = 0.09) at 12-week follow-up.

Characteristics Associated with Cotinine-Confirmed (Version 2) 12-Week Abstinence Across Groups

Sociodemographic factors were not associated with abstinence at 12 weeks. Participants with lower baseline

TABLE 2. Baseline Smoking Characteristics

Variable	All ($N = 49$)	Control ($N = 17$)	Intervention ($N = 32$)	p
Smoking characteristics				
Years smoked, mean (SD)	37.8 (13.9)	34.1 (13.7)	39.7 (13.8)	0.18
Cigarettes per day, mean (SD)	16.4 (11.6)	15.4 (9.0)	17.0 (12.8)	0.65
Smoke within 30 min of waking (%)	76.6	73.3	78.1	0.72
Past cessation treatment (%)				
Any counseling	31.0	41.7	26.7	0.46
Any pharmacotherapy	64.4	73.3	60.0	0.38
Nicotine replacement therapy	44.4	50.0	41.9	0.75
Varenicline	34.8	43.8	30.0	0.52
Bupropion	25.0	33.3	21.4	0.45
Live with a smoker (%)	34.7	35.3	34.4	0.95
Allows smoking in home (%)	87.8	94.1	84.4	0.33
Importance of quitting, mean (SD)[a]	8.9 (2.5)	8.1 (3.1)	9.3 (2.0)	0.12
Confidence in ability to quit, mean (SD)[b]	5.9 (2.8)	5.4 (3.0)	6.3 (2.6)	0.28
Knowledge about smoking and cancer, mean (SD)[c]				
Quitting will reduce treatment complications	8.9 (2.0)	8.6 (2.6)	9.0 (1.8)	0.56
Quitting will result in living longer	9.3 (1.5)	9.4 (1.4)	9.2 (1.5)	0.73
Quitting will reduce likelihood of future tumors	8.9 (2.0)	8.7 (1.9)	9.0 (2.1)	0.62

[a] Importance of quitting, 1–10 scale; 1 = not at all, 10 = very important.
[b] Confidence in ability to quit, 1–10 scale; 1 = not at all, 10 = very confident.
[c] Knowledge about smoking and cancer, 0–10 scale; 0 = not at all, 10 = very much.

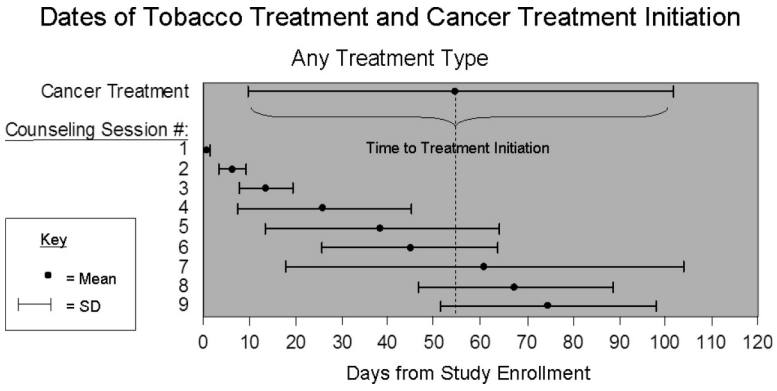

FIGURE 2. Timeline of smoking cessation counseling sessions and cancer treatment initiation.

TABLE 3. Smoking Outcomes

	All ($N = 46$)	Intervention ($N = 32$)	Control ($N = 14$)	OR (95% CI)
7-d point prevalence tobacco abstinence				
2 wk				
Self-reported	17/46 (37.0%)	13/32 (40.6%)	4/14 (28.6%)	1.23 (0.34–4.52)
Cotinine-confirmed (version 1)[a]	16/46 (34.8%)	12/32 (37.5%)	4/14 (28.6%)	1.50 (0.38–5.86)
Cotinine-confirmed (version 2)[b]	11/46 (23.9%)	9/32 (28.1%)	2/14 (14.3%)	2.35 (0.44–12.64)
12 wk				
Self-reported quit	17/46 (37.0%)	14/32 (43.8%)	3/14 (21.4%)	2.85 (0.67–12.22)
Cotinine-confirmed (version 1)[a]	15/46 (32.6%)	13/32 (40.6%)	2/14 (14.3%)	4.11 (0.79–21.48)
Cotinine-confirmed (version 2)[b]	13/46 (28.3%)	11/32 (34.4%)	2/14 (14.3%)	3.14 (0.59–16.62)

[a] Analysis with insufficient returned saliva samples counted as nonsmokers.
[b] Analysis with insufficient returned saliva samples counted as smokers.
OR, odds ratio; CI, confidence interval.

levels of depressive symptoms were more likely to be abstinent (OR = 0.81, 95% CI = 0.67–0.98, $p = 0.03$). There were trends associating 12-week abstinence with smoking within 30 minutes of waking (OR= 3.86, 95% CI = 0.87–17.16, $p = 0.08$), believing that quitting smoking was important (OR = 1.28, 95% CI = 0.94–1.75, $p = 0.11$) and that continued smoking caused surgical complications (OR = 1.56, 95% CI = 0.87–2.79, $p = 0.14$). Receiving a cancer diagnosis by the end of the study period (OR = 4.05, 95% CI = 0.77–21.26, $p = 0.10$) and having surgery (OR = 3.05, 95% CI = 0.78–1.96, $p = 0.11$) were marginally associated with 12-week abstinence. Time to treatment was not associated with 12-week abstinence (OR = 0.99, 95% CI = 0.98–1.01, $p = 0.48$). An increase in quit confidence from baseline to follow-up was associated with 12-week abstinence (OR = 1.74, 95% CI = 1.06–2.88, $p = 0.03$).

DISCUSSION

The current study is, to our knowledge, the first controlled study of a combined behavioral and pharmacological tobacco treatment program targeting patients at their entry into thoracic surgery and thoracic oncology clinics. We found that the program was feasible and acceptable. Furthermore, the intervention produced higher biochemically validated smoking cessation rates at the end of treatment, although the difference did not reach statistical significance due to the small sample size of this pilot study.

Our findings show that those who continue smoking after a lung cancer diagnosis are a challenging population with a long smoking history, high nicotine dependence, and low confidence to quit. This indicates that this particular population of smokers likely needs intensive tobacco treatment, preferably one that combines pharmacological support with extended counseling to achieve abstinence.

We were able to enroll almost half of the eligible patients at their entry into the thoracic oncology setting, a rate similar to previous smoking cessation studies that enrolled patients after cancer treatment.[33] Enrolling as early as possible is critical because the closer to the time of diagnosis that smoking cessation treatment is delivered, the greater the health benefits, including reduced perioperative morbidity, and the higher the likelihood for continued abstinence.[2,4,5,32,45] The main reasons for refusal, reluctance to take varenicline and wanting to quit unassisted, could represent quitting preferences, but these could also be proxies for not wanting to quit. Another factor to consider is that during the study enrollment period, varenicline received a black box warning about psychiatric side effects, which may have caused some reluctance in smokers.[46]

We were able to engage patients in tobacco treatment during a vulnerable and critical period. The program length matched the USPHS recommended 90 minutes of contact time, but the number of contacts exceeded the USPHS minimum recommended number of sessions, which are usually offered for telephone-delivered smoking cessation interventions.[22,24,47] These patients seemed to need frequent, brief contacts and social support to promote tobacco abstinence.

Despite initial concerns that cancer patients might not tolerate varenicline due to side effects similar to cancer treatment side effects (e.g., nausea), participant adherence rates to varenicline were similar to nicotine replacement therapy (NRT) use in cancer patients and noncancer patients.[48,49] Similar to varenicline in the general population, nausea was the most common side effect that is reported in one-third of the participants.

This study had several limitations. The generalizability of the findings was limited by using only a single study site. The statistical power to detect differences was limited by the small sample size of this pilot study. Although the sample size cannot be increased in accordance to power calculations that would enable detection of a statistically significant difference, we believe that the encouraging nonstatistical trend provides a rationale for an adequately powered RCT. Its nonrandomized design leaves open the potential for unmeasured confounding due to group dissimilarities.

Despite these limitations, our combined behavioral and varenicline intervention produced promising feasibility and potential efficacy results. In pursuit of a larger scale randomized trial to assess the efficacy of our counseling plus varenicline treatment, we recommend comparison of two treatment arms: an "intensive" counseling plus varenicline versus a "brief" counseling plus varenicline. A counseling only or varenicline only comparison group would not be in compliance with clinical practice guidelines. In addition, a counseling only comparison would not build on this work, which supported the tolerability of varenicline in this population, and given the psychological and medical vulnerability of this population, it is not preferable to use a varenicline only comparison.

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